K093819

JUN - 9 2010

7 510(k) Summary

Submitter:	ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439
Contact Person:	Tom Speikers Director, Quality Systems and Regulatory Affairs ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439 Phone: 952-646-3168 Fax: 952-646-3110 speikerst@ARKRAYusa.com
Date Prepared:	December 11, 2009
Trade Name:	ARKRAY Diabetes Data Management Software (SMBG Viewer)
Classification:	Glucose test system, 21 CFR 862.1345; Class II, and 21 CFR 862.2100, Class I.
Product Codes:	CGA, NBW, JQP.
Predicate Device:	GlucoBalance Data Management Software (K022545).
Device Description:	The ARKRAY Diabetes Data Management Software is an optional accessory for use with ARKRAY blood glucose meters with data management capabilities. The subject device consists of a USB data transfer cable and software. The system allows the user to download blood glucose results from their glucose meter to their computer, maintain a history of their glucose test results, and convert them into graphs, charts and reports. The software does not recommend any medical treatment or medication dosage level.
Intended Use:	The ARKRAY Diabetes Data Management Software (SMBG Viewer) is an optional accessory for use with ARKRAY blood glucose meters with data management capabilities. The ARKRAY Diabetes Data Management Software transfers data from the meter's memory into a computer for enhanced data management. The ARKRAY Diabetes Data Management Software is intended for use in home and clinical settings to assist people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support diabetes management.
Functional and Safety Testing:	A full array of in-house testing was done consistent with relevant FDA guidance's for blood glucose monitoring systems. Testing included validation of the systems hardware (USB data transfer cable) and software as well as consumer studies that demonstrated the systems ability to be easily operated by in-home users.
Conclusion:	Labeling, validation testing results and consumer studies results support the Indications for Use and the claim of substantial equivalence to the predicate (K022545).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

ARKRAY Factory USA, Inc
c/o Tom Speikers
Director, Quality Systems and Regulatory Affairs
5182 West 76th St.,
Minneapolis, MN 55439

JUN 09 2010

Re: k093819
Trade/Device Name: ARKRAY Diabetes Data Management Software (SMBG Viewer)
Regulation Number: 21 CFR 862.1345
Regulation Name:Glucose test system.
Regulatory Class: II
Product Code: NBW, CGA, JQP
Dated: April 8, 2010
Received: April 27, 2010

Dear: Mr. Speikers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

6 Indications for Use Statement

510(k) Number (if known): K093819

Device Name: ARKRAY Diabetes Data Management Software

Indications For Use:

ARKRAY Diabetes Data Management Software:
The ARKRAY Diabetes Data Management Software (SMBG Viewer) is an optional accessory for use with ARKRAY blood glucose meters with data management capabilities. The ARKRAY Diabetes Data Management Software transfers data from the meter's memory into a computer for enhanced data management. The ARKRAY Diabetes Data Management Software is intended for use in home and clinical settings to assist people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support diabetes management.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K093819

6 Indications for Use Statement

510(k) Number (if known): K093819

Device Name: ARKRAY Diabetes Data Management Software

Indications For Use:

ARKRAY Diabetes Data Management Software:
The ARKRAY Diabetes Data Management Software (SMBG Viewer) is an optional accessory for use with ARKRAY blood glucose meters with data management capabilities. The ARKRAY Diabetes Data Management Software transfers data from the meter's memory into a computer for enhanced data management. The ARKRAY Diabetes Data Management Software is intended for use in home and clinical settings to assist people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support diabetes management.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K093819